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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,211	03/25/2002	William E Hintz	2847-62447	4982

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EXAMINER

STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 11/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/089,211	Applicant(s) HINTZ ET AL.	
	Examiner David J Steadman	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-7, 10, 24-27, 29 and 30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-7, 10, 24-27, 29 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/25/02</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

- [1]** Claims 3-7, 10, 24-27, and 29-30 are pending in the application.
- [2]** Applicants' amendment to the claims, filed September 13, 2004, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.
- [3]** Applicants' amendment to the specification, filed September 13, 2004, is acknowledged.
- [4]** Receipt of a sequence listing in computer readable form (CRF), a paper copy thereof, a statement of their sameness, and a statement that no new matter has been added to the specification by the paper copy of the sequence CRF, all filed November 04, 2004, is acknowledged.
- [5]** Receipt of reference Database EMBL Accession Number Q12563 and reference Herscovics et al., filed September 13, 2004, is acknowledged.
- [6]** Applicants' arguments filed September 13, 2004 have been fully considered and are deemed to be persuasive to overcome some of the rejections and/or objections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.
- [7]** The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Sequence Compliance

[8] The instant application contains at least one nucleic acid and/or amino acid sequence that is encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). Applicants have satisfied the requirements for sequence compliance, *i.e.*, the application contains a computer readable form (CRF) of the sequence listing, a paper copy thereof, a statement that the CRF and paper copy of the sequence listing are identical, and, as the sequence listing is a substitute sequence listing, a statement that the paper copy of the substitute sequence listing contains no new matter.

Information Disclosure Statement

[9] In view of applicants' submission of references Database EMBL Accession Number Q12563 and Herscovics et al., all references cited by applicants in the information disclosure statement filed March 25, 2002 have been considered by the examiner. A copy of the information disclosure statement is attached to the instant Office action.

Priority

[10] Applicant's claim for domestic priority under 35 USC § 119(e) to provisional application 60/157,341, filed October 01, 1999, is acknowledged. The examiner can find no disclosure of the sequences of SEQ ID NO:17 and 18 in provisional application 60/157,341. In the absence of evidence to the contrary, applicant is granted ONLY the

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benefit of the earlier filing date of PCT/US00/27210, filed October 02, 2000, to the extent this application provides support for the claimed subject matter.

Claim Rejections - 35 USC § 101

[11] The utility rejection of claims 3-7, 10, 24-27, and 29-30 under 35 U.S.C. 101 and the corresponding enablement rejection of claims 3-7, 10, 24-27, and 29-30 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record as set forth at items [8] and [11], respectively, of the Office action mailed March 08, 2004 and for the reasons stated below.

RESPONSE TO ARGUMENT: Applicants argue the requirements for patentable utility have been satisfied. In particular, applicants argue the asserted utility for the claimed invention, *i.e.*, modifying protein glycosylation, is substantial as there is a real-world use for mannosidases – namely, to alter specific properties of proteins such as intercellular trafficking, aggregation, and antigenicity. Applicants' argument is not found persuasive.

It is the examiner's position that the asserted utility of the claimed nucleic acid for encoding a protein that modifies protein glycosylation is not specific and substantial as the asserted utility would require additional experimentation before a skilled artisan can find a "real-world" use for the claimed nucleic acid. As stated in a previous Office action, and undisputed by applicants, mannosidases comprise a highly diverse group of enzymes having a variety of enzymatic activities (see Appendix C of the Office action mailed March 08, 2004) and the specification fails to disclose the particular

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mannosidase activity and substrate of the polypeptide of SEQ ID NO:18, encoded by SEQ ID NO:17. As such, further experimentation is required for a skilled artisan to use the claimed polynucleotide. This type of utility is not considered a "substantial utility". See e.g., *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966). The specification must teach a skilled artisan how to use what is claimed and not merely provide a blueprint for further experimentation in order for an artisan to identify a use for the claimed invention. As stated in *Brenner v. Manson*, 383 U.S. 519 535-536, 148 USPQ 689, 696 (1966), "[a] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion". Here the specification fails to provide a specific benefit in currently available form for the claimed nucleic acid as additional research is required (as evidenced by Eades et al. (of record)) in order to use the nucleic acid according to the asserted utility as set forth in the specification.

Claim Rejections - 35 USC § 112, First Paragraph

[12] The written description rejection of claims 3-7, 10, 24-26, and 29 under 35 U.S.C. 1112, first paragraph, is maintained for the reasons of record as set forth at item [10] of the Office action mailed March 08, 2004 and for the reasons stated below.

RESPONSE TO ARGUMENT: Applicants argue the claims have been amended to recite 80% sequence identity. Applicants argue the specification provides adequate written description for the claimed nucleic acids, citing pp. 11-15 and further argue a "sequence comparison is provided at page 33-38." Applicants' argument is not found persuasive.

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The examiner maintains the position that the single disclosed representative species of nucleic acids, *i.e.*, SEQ ID NO:17, fails to represent all species encompassed by the genus. As stated in a previous Office action and undisputed by applicants, the genus of claimed nucleic acids encompasses species that are widely variant in both structure and function, including (but not limited to) genomic sequences, allelic variants, and nucleic acid variants encoding polypeptides having function other than the alpha-1,2-mannosidase activity of SEQ ID NO:18, *e.g.*, non-functional polypeptides and polypeptides having activity other than the asserted alpha-1,2-mannosidase activity, including the numerous mannosidase activities known in the art (see Appendix C of the Office action mailed March 08, 2004). It should be noted that even the asserted activity of SEQ ID NO:18, *i.e.*, alpha-1,2-mannosidase activity, encompasses at least two distinct mannosidase enzymatic activities (see Appendix C of the Office action mailed March 08, 2004). Moreover, regarding the genus of recited macromolecules having an altered glycosylation pattern as made by the method of claim 10, as noted above, this genus is widely variant with respect to both structure and function. Again the specification discloses only a single representative species of the recited genus of macromolecules having an altered glycosylation pattern, *i.e.*, a method for releasing mannose from the substrate mannose-alpha-1,2-mannose-alpha-O-CH₃. Given the lack of description of a representative number of polynucleotides and macromolecules, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicant was in possession of the claimed invention.

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It should be noted that it is not clear to the examiner as to whether the "sequence comparison" that is referenced by applicants in the instant response was meant to be included with the instant response, or is part of the specification. If part of the specification, it is noted that pp. 33-38 of the specification do not disclose a sequence comparison.

[13] Even if a polynucleotide encoding SEQ ID NO:18 is found to have patentable utility, the following rejection is still maintained. The scope of enablement rejection of claims 3-7, 10, 24-26, and 29 under 35 U.S.C. 1112, first paragraph, is maintained for the reasons of record as set forth at item [10] of the Office action mailed March 08, 2004 and for the reasons stated below.

RESPONSE TO ARGUMENT: Applicants argue the claims have been amended to recite 80% sequence identity. Applicants further argue a "sequence comparison is provided at page 33-38." Applicants' argument is not found persuasive.

As stated in a previous Office action, the claims encompass a broad scope of claimed nucleic acids and recited macromolecules. The specification discloses only a single working example of the broad scope of claimed nucleic acids, *i.e.*, SEQ ID NO:17, and only a single working example of the broad scope of recited macromolecules having an altered glycosylation pattern, *i.e.*, a method for releasing mannose from the substrate mannose- α -1,2-mannose- α -O-CH₃, and fails to provide guidance for altering the nucleic acid of SEQ ID NO:17 with an expectation of obtaining an encoded polypeptide having any mannosidase enzymatic activity (see Appendix C of the Office action mailed March 08, 2004), including the asserted α -

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1,2-mannosidase activity (of which at least 2 distinct activities are known in the art as stated above). It should be noted that applicants do not dispute the high level of unpredictability as evidenced by Branden et al. (of record) and Witkowski et al. (of record). In view of the overly broad scope of the claims, the lack of guidance and working examples provided in the specification, the high level of unpredictability as evidenced by the prior art, and the amount of experimentation that is required, it is the examiner's position that undue experimentation is necessary for a skilled artisan to make and use the entire scope of the claimed invention. See also the detailed analysis of the Factors of *In re Wands* as set forth at pp. 10-13 of the Office action mailed March 08, 2004.

It should be noted that it is not clear to the examiner as to whether the "sequence comparison" that is referenced by applicants in the instant response was meant to be included with the instant response, or is part of the specification. If part of the specification, it is noted that pp. 33-38 of the specification do not disclose a sequence comparison.

Claim Rejections - 35 USC § 102

[14] In view of the amendment to the claims, the rejection of claim(s) 11, 20-23, and 28 under 35 U.S.C. 102(b) as being anticipated by Database GenBank Accession Number AA965900 (GI:3139784) is withdrawn. Claims 11, 20-23, and 28 have been canceled by the instant claim amendment.

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Conclusion

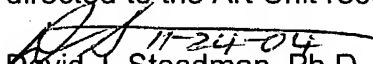
[15] Status of the claims:

- Claims 3-7, 10, 24-27, and 29-30 are pending.
- Claims 3-7, 10, 24-27, and 29-30 are rejected.
- No claim is in condition for allowance.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (571) 272-0942. The Examiner can normally be reached Monday-Friday from 7:00 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The FAX number for submission of official papers to Group 1600 is (703) 308-4242. Draft or informal FAX communications should be directed to (571) 273-0942. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.


David J. Steadman, Ph.D.
Patent Examiner
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